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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/057,197	10/26/2001	Martin J. Wensley	509032001500	1701

7590 01/12/2005

Mika Mayer
Morrison & Foerster LLP
755 Page Mill Road
Palo Alto, CA 94304-1018

EXAMINER	
EREZO, DARWIN P	

ART UNIT	PAPER NUMBER
3731	

DATE MAILED: 01/12/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/057,197	WENSLEY ET AL.	
	Examiner	Art Unit	
	Darwin P. Erezo	3731	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *30 September 2004*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *10-13,15,29,31-35,37-43,48-53,56,57,65 and 124-130* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☒ Claim(s) *10,11,39-43,48 and 124-130* is/are allowed.

6)☒ Claim(s) *12,15,29,31-35,37,38,49-53,56,57 and 65* is/are rejected.

7)☒ Claim(s) *13* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Claim Rejections - 35 USC § 102

1. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

2. Claims 12 and 15 are rejected under 35 U.S.C. 102(b) as being anticipated by US 2004/0016427 to Byron et al.

(claim 12) Byron teaches a method for generating an aerosol comprising the steps of moving a physiologically active compound into a heating-vaporization zone (paragraph 34) and heating the compound to vaporize at least a portion of the compound (paragraph 34); and mixing the resulting vapor with a gas, in a ratio (paragraph 56; the gas within the spacer chamber), wherein the ratio of vapor to gas is controlled by regulating the rate of vaporization (paragraph 51) and wherein the vaporization rate is controlled by changing the rate the compound is moved into the zone (intermittently) to form a desired particle size when a stable concentration of particles in the gas is reached.

(claim 15) Byron also teaches heating the physiologically active compound at a temperature below the boiling point (paragraph 34).

Claim Rejections - 35 USC § 103

3. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

4. Claims 29, 50, 52, 56, 57 and 65 are rejected under 35 U.S.C. 103(a) as being unpatentable over US 5,146,915 to Montgomery in view of US 5,894,841 to Voges.

(claim 29) Montgomery teaches a method for generating an aerosol comprising the steps of depositing a compound into a substrate (the vaporizing chamber **12** of Montgomery) prior to heating, sweeping gas across the film (via carrier gas, col. 2, lines 33-58); heating the compound to vaporize the compound (via heaters **32**).

Montgomery is silent with regards to the method comprising the step of mixing the vapor with the carrier gas in a ratio to form a desired particle size when a stable concentration of particles in the gas is reached.

Voges teaches that the droplet size of an aerosol delivered to a patient is a function of the carrier gas pressure and velocity (col. 1, lines 43-55).

Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the method of Montgomery to include the step of mixing the resulting vapor with a carrier gas in a ratio to form a desired particle size since Voges teaches that it is well known in the art to control the particle size since the particle size is a function of the delivered pressure and velocity of the carrier gas, i.e., controlling the pressure and velocity of the carrier gas will alter the ratio of vapor to

carrier gas. Furthermore, constant application of the same pressure and velocity of the carrier gas would produce aerosol with the same particle size, thus producing a stable concentration (inherent via the function of the pressure and velocity of the carrier gas in relation to the vapor).

(claims 50, 52, 56, 57 and 65) Montgomery teaches a substrate that is heated sequentially (heater 32 has two prongs that are in sequence; a connected series); wherein the heaters are of the resistive/conductive type; and wherein the aerosol is administered to a patient.

5. Claims 31-35, 37, 38 and 53 are rejected under 35 U.S.C. 103(a) as being unpatentable over US 5,146,915 to Montgomery in view of US 5,894,841 to Voges, and in further view of US 5,366,770 to Wang.

Montgomery teaches all the limitations of the claims, as recited in the rejection above, but fails to teach the compound being heated by moving the substrate through an alternating magnetic field (inductive). Wang teaches a vaporizer using magnetic fields to heat a compound (col. 4, lines 53-59) and the use of a mesh, metallic or stainless steel foil (col. 6, lines 51-54). Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to use any well known heat step, including the heating step of Wang, since the applicant has not disclosed that the specific type of heating step solves any stated problems or is for any particular purpose and it appears that the invention would perform equally well with the step taught by Wang.

Wang teaches the field maintained at 1 MHz but is silent with regards to 100-300 kHz. However, it would have been obvious to one of ordinary skill in the at the time the invention was made to have the thickness in the recited range because it has been held that where the general conditions of a claim are disclosed in the prior art, discovering the optimum or workable ranges involves only routine skill in the art. *In re Aller,* 105 USPQ 233.

6. Claims 49 and 51 are rejected under 35 U.S.C. 103(a) as being unpatentable over Montgomery in view of Voges, and in further view of US 6,090,212 to Mahawili.

Montgomery teaches a substrate that is heated sequentially (heater 32 has two prongs that are in sequence; a connected series). However, the above combination of Montgomery/Voges is silent with regards to a heater means comprising changing the focus of photon energy. Mahawili teaches a heater wherein the photon energy is used to provide heat. Therefore, it would have been obvious at the time the invention was made to use the heater of Mahawili in the method of Montgomery/Vogue, since it is well within the scope of one ordinary skill in the art to replace Montgomery's heater with any well known heater, including the heater of Mahawili.

Allowable Subject Matter

7. Claims 10, 11, 39-43, 48 and 124-130 are allowed.

8. Claim 13 is objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Response to Arguments

The indication of allowable subject matter in the previous office action is regretted and new grounds of rejections are set forth.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Darwin P. Erezo whose telephone number is (571) 272-4695. The examiner can normally be reached on M-F (8:30-5:00).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anhtuan T. Nguyen can be reached on (571) 272-4963. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

GLENN K. DAWSON
PRIMARY EXAMINER

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